

# United States Senate

April 20, 2020

Miles D. White  
Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, Illinois 60064

Dear Miles D. White,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for 13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

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<sup>1</sup> <https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/>

<sup>2</sup> *Id.*

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[https://www.michigan.gov/coronavirus/0,9753,7-406-98163\\_98173---,00.html](https://www.michigan.gov/coronavirus/0,9753,7-406-98163_98173---,00.html)

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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/s/ Thomas R. Carper

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Richard J. Durbin

United States Senator

/s/ Maize K. Hirono

United States Senator

/s/ Tammy Baldwin

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Benjamin L. Cardin

United States Senator

/s/ Edward J. Markey

United States Senator

/s/ Cory A. Booker

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Richard A. Gonzalez  
Abbvie Inc. Headquarters  
1 N. Waukegan Road  
North Chicago, Illinois 60064

Dear Richard A. Gonzalez,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

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/s/ Chris Van Hollen

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/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

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United States Senator

/s/ Benjamin L. Cardin

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/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Robert A. Bradway  
Amgen Corporate Headquarters  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1799

Dear Robert A. Bradway,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

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As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

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/s/ Chris Van Hollen

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/s/ Thomas R. Carper

United States Senator

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United States Senator

/s/ Cory A. Booker

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Pascal Soriot  
AstraZeneca  
1800 Concord Pike  
Wilmington, DE 19803

Dear Pascal Soriot,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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United States Senator

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United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Werner Baumann  
Bayer Corporation  
100 Bayer Boulevard  
Whippany, NJ 07981

Dear Werner Baumann,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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<sup>8</sup> <https://www.census.gov/quickfacts/fact/table/detroitcitymichigan,US/PST045218>;  
[https://www.michigan.gov/coronavirus/0,9753,7-406-98163\\_98173---,00.html](https://www.michigan.gov/coronavirus/0,9753,7-406-98163_98173---,00.html)

<sup>9</sup> *Id.*; <https://www.cnn.com/2020/04/07/us/coronavirus-black-americans-race/index.html>

<sup>10</sup> <https://www.jhscipolgroup.org/blog-1/2017/9/6/diversity-in-clinical-trials>

<sup>11</sup> *Id.*

<sup>12</sup> <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-addresses-health-disparities-through-communication-research-and-collaboration>

<sup>13</sup> *Id.*

/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Richard J. Durbin

United States Senator

/s/ Benjamin L. Cardin

United States Senator

/s/ Maize K. Hirono

United States Senator

/s/ Edward J. Markey

United States Senator

/s/ Tammy Baldwin

United States Senator

/s/ Cory A. Booker

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Paul Perreault  
CSL Behring Global Headquarters  
1020 First Avenue  
King of Prussia, PA 19406-0901

Dear Paul Perreault,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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<sup>3</sup> [https://www.nj.gov/health/cd/documents/topics/NCOV/COVID\\_Confirmed\\_Case\\_Summary.pdf](https://www.nj.gov/health/cd/documents/topics/NCOV/COVID_Confirmed_Case_Summary.pdf)

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13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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<sup>13</sup> *Id.*

/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Richard J. Durbin

United States Senator

/s/ Benjamin L. Cardin

United States Senator

/s/ Maize K. Hirono

United States Senator

/s/ Edward J. Markey

United States Senator

/s/ Tammy Baldwin

United States Senator

/s/ Cory A. Booker

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

David A. Ricks  
Eli Lilly and Company Global Headquarters  
Lilly Corporate Center  
Indianapolis, Indiana 46285

Dear David A. Ricks,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Richard J. Durbin

United States Senator

/s/ Benjamin L. Cardin

United States Senator

/s/ Maize K. Hirono

United States Senator

/s/ Edward J. Markey

United States Senator

/s/ Tammy Baldwin

United States Senator

/s/ Cory A. Booker

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Alexander Hardy  
Genentech, Inc.  
1 DNA Way  
South San Francisco, CA 94080

Dear Alexander Hardy,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Richard J. Durbin

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/s/ Benjamin L. Cardin

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/s/ Maize K. Hirono

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United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator



# United States Senate

April 20, 2020

Daniel O'Day  
Gilead  
333 Lakeside Drive  
Foster City, CA 94404

Dear Daniel O'Day,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

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Sincerely,

/s/ Robert Menendez

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/s/ Chris Van Hollen

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<sup>9</sup> *Id.*; <https://www.cnn.com/2020/04/07/us/coronavirus-black-americans-race/index.html>

<sup>10</sup> <https://www.jhscipolgroup.org/blog-1/2017/9/6/diversity-in-clinical-trials>

<sup>11</sup> *Id.*

<sup>12</sup> <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-addresses-health-disparities-through-communication-research-and-collaboration>

<sup>13</sup> *Id.*

/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Richard J. Durbin

United States Senator

/s/ Benjamin L. Cardin

United States Senator

/s/ Maize K. Hirono

United States Senator

/s/ Edward J. Markey

United States Senator

/s/ Tammy Baldwin

United States Senator

/s/ Cory A. Booker

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Emma Walmsley  
GSK US Corporate Headquarters  
Philadelphia Navy Yard  
5 Crescent Drive  
Philadelphia, PA 19112

Dear Emma Walmsley,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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<sup>2</sup> *Id.*

<sup>3</sup> [https://www.nj.gov/health/cd/documents/topics/NCOV/COVID\\_Confirmed\\_Case\\_Summary.pdf](https://www.nj.gov/health/cd/documents/topics/NCOV/COVID_Confirmed_Case_Summary.pdf)

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<sup>5</sup> <https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/>

<sup>6</sup> *Id.*

<sup>7</sup> <https://www.washingtonpost.com/nation/2020/04/07/chicago-racial-disparity-coronavirus/>

13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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<sup>8</sup> <https://www.census.gov/quickfacts/fact/table/detroitcitymichigan,US/PST045218>;  
[https://www.michigan.gov/coronavirus/0,9753,7-406-98163\\_98173---,00.html](https://www.michigan.gov/coronavirus/0,9753,7-406-98163_98173---,00.html)

<sup>9</sup> *Id.*; <https://www.cnn.com/2020/04/07/us/coronavirus-black-americans-race/index.html>

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<sup>12</sup> <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-addresses-health-disparities-through-communication-research-and-collaboration>

<sup>13</sup> *Id.*

/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Richard J. Durbin

United States Senator

/s/ Benjamin L. Cardin

United States Senator

/s/ Maize K. Hirono

United States Senator

/s/ Edward J. Markey

United States Senator

/s/ Tammy Baldwin

United States Senator

/s/ Cory A. Booker

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Alex Gorsky  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, New Jersey 08933

Dear Alex Gorsky,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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<sup>7</sup> <https://www.washingtonpost.com/nation/2020/04/07/chicago-racial-disparity-coronavirus/>

13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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<sup>13</sup> *Id.*



/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Richard J. Durbin

United States Senator

/s/ Benjamin L. Cardin

United States Senator

/s/ Maize K. Hirono

United States Senator

/s/ Edward J. Markey

United States Senator

/s/ Tammy Baldwin

United States Senator

/s/ Cory A. Booker

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Vasant Narasimhan  
Novartis Institutes for Biomedical Research Inc.  
250 Massachusetts Avenue  
Cambridge, MA 02139

Dear Vasant Narasimhan,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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<sup>13</sup> *Id.*

/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Richard J. Durbin

United States Senator

/s/ Benjamin L. Cardin

United States Senator

/s/ Maize K. Hirono

United States Senator

/s/ Edward J. Markey

United States Senator

/s/ Tammy Baldwin

United States Senator

/s/ Cory A. Booker

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Albert Bourla  
Pfizer Inc.  
235 East 42nd Street  
New York, NY 10017-5755

Dear Albert Bourla,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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<sup>7</sup> <https://www.washingtonpost.com/nation/2020/04/07/chicago-racial-disparity-coronavirus/>

13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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<sup>13</sup> *Id.*

/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal

United States Senator

/s/ Robert P. Casey

United States Senator

/s/ Richard J. Durbin

United States Senator

/s/ Benjamin L. Cardin

United States Senator

/s/ Maize K. Hirono

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/s/ Edward J. Markey

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/s/ Tammy Baldwin

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/s/ Cory A. Booker

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Leonard Schleifer  
Regeneron Pharmaceuticals  
777 Old Saw Mill River Rd  
Tarrytown, NY 10591

Dear Leonard Schleifer,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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<sup>1</sup> <https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/>

<sup>2</sup> *Id.*

<sup>3</sup> [https://www.nj.gov/health/cd/documents/topics/NCOV/COVID\\_Confirmed\\_Case\\_Summary.pdf](https://www.nj.gov/health/cd/documents/topics/NCOV/COVID_Confirmed_Case_Summary.pdf)

<sup>4</sup> <https://www.census.gov/quickfacts/NJ>

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13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>8</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>9</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>10</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>11</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>12</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>13</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue.

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

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<sup>8</sup> <https://www.census.gov/quickfacts/fact/table/detroitcitymichigan,US/PST045218>;  
[https://www.michigan.gov/coronavirus/0,9753,7-406-98163\\_98173---,00.html](https://www.michigan.gov/coronavirus/0,9753,7-406-98163_98173---,00.html)

<sup>9</sup> *Id.*; <https://www.cnn.com/2020/04/07/us/coronavirus-black-americans-race/index.html>

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<sup>12</sup> <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-addresses-health-disparities-through-communication-research-and-collaboration>

<sup>13</sup> *Id.*

/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

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/s/ Robert P. Casey

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/s/ Cory A. Booker

United States Senator

/s/ Bernard Sanders

United States Senator

/s/ Sherrod Brown

United States Senator

/s/ Amy Klobuchar

United States Senator

/s/ Mark R. Warner

United States Senator

# United States Senate

April 20, 2020

Paul Hudson  
Sanofi US Headquarters  
55 Corporate Drive  
Bridgewater, NJ 08807

Dear Paul Hudson,

We write to request that you ensure that any vaccine or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>1</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>2</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>3</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>4</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>5</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>6</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>7</sup> In Michigan, African Americans account for

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